REMARKS

The foregoing amendment is submitted to more clearly set forth the claimed invention and to highlight the differences between the claimed invention and the cited prior art.

The invention is now characterized as a device which includes three principal components. The first component is a substrate for supporting an indicating agent. The second component is the indicating agent which generates a desired detectable signal as explained hereinafter. The third component is a protective coating. The protective coating is permanently affixed to the device including during the assay and covers the indicating agent to protect the same from the ambient environment. In particular, the protective coating is comprised of a protective coating forming material which is impervious to the penetration of at least one gas which is capable of adversely affecting the indicating agent. In addition, the protective coating does not itself generate an adverse amount of undesired signals and furthermore is at least substantially transparent to any excitation wavelength necessary to excite the indicating agent as well as the desired detectable signal generated by the indicating agent. The device is suitable for use in an assay for the detection of substance in a sample suspected of containing the same.

Thus, claim 1 focuses on the device suitable for use in an assay in which the substrate, indicating agent and protective coating are the principle components thereof.

Support for the description of the substrate and the indicating agent as now set forth in amended claim 1 is found throughout the specification and furthermore is commonly employed in most type of assays. Of particular importance to the claimed invention is the protective coating. There are three aspects of the protective coating that make the present invention a significant advance in the assay art and unobvious from the prior art of record.

First, the protective coating is permanently affixed to the device including during the assay and covers the indicating agent. This aspect of the protective coating is apparent from the examples and particularly Example 2 on page 19 describing the preparation of a microarray substrate (i.e. an example of the device suitable for use in an assay). In particular after all components were included in the device, the substrate was dried and only thereafter the protective coating was applied as the last step to complete the device. Once the protective coating was applied, it remained in place for as long as necessary to conduct the assay. Thus, the protective coating of the present invention protects the indicating agent at all times even during the assay.

The second aspect of the protective coating is that it must be impervious to gases which can adversely affect the indicating agent. The protective coating protects the indicating agent at all times from attack by atmospheric gases including ozone (page 12, lines 7-11).

The protective coating itself does not generate an adverse amount of undesirable signals. This aspect of the protective coating is described at page 12, lines 11-14. In addition, the protective coating is at least substantially transparent to any excitation wavelengths necessary to excite the indicating agent as well as to the desired detectable signal which is generated by the indicating agent when contacted by the substance in a sample suspected of containing the same. Thus, the present invention is directed to a self-contained device in which all of the materials necessary for conducting an assay are contained in the device and which includes a protective coating to protect the indicating agent so that it does not degrade due to exposure to external environmental agents such as ozone. The protective coating is made of materials that do not generate interfering signals while allowing excitation wavelengths to pass therethrough as well as the detectable signal, without adversely affecting the same.

Referring to the Office Action, claims 12-15 have been rejected under 35 U.S.C. Section 112, second paragraph. These claims have been canceled because in essence they are directed to the protective coating composition per se and therefore are the subject matter of the non-elected invention. Withdrawal of the

rejection under 35 U.S.C. Section 112 is therefore deemed proper and is respectfully requested.

Claims 1-2, 5-8 and 12-16 stand rejected as anticipated by Gagnon (U.S. Patent No. 5,470,757), Marino (U.S. Patent No. 4,981,653) or Lawrence (U.S. Patent No. 5,571,684). In addition, claims 1-8 and 12-16 stand rejected as anticipated by Barmore (U.S. Patent No. 5,483,819). Claims 3 and 4 and claims 9-11 stand rejected as obvious over the combination of these references. The rejection is hereby traversed and reconsideration is respectfully requested.

As previously indicated, the device of the present invention requires a protective coating having four essential characteristics. The protective coating is in place when the assay is performed and thus it is affixed to the device during the assay. Second, the protective coating is impervious to the penetration of at least one gas which can adversely affect the indicating agent. Third, the protective coating allows excitation wavelengths to pass therethrough and fourth, allows the desired detectable signal generated by the indicating agent to also pass therethrough.

Gagnon (U.S. Patent No. 5,470,757) describes a sample holder for use in infrared spectrophotometric analysis. The holder comprises a microporous sheet (column 4, lines 3-5). The purpose of the microporous sheet and polymer films

forming the same is to enable the liquid sample to wet out the sheet, facilitating spectroscopic analysis (column 4, lines 50-65).

The purpose of the microporous structure is to enable a liquid or gaseous sample to enter the micropores. This is not the type of material that would be used in the present invention. The purpose of the protective coating is to protect the indicating agent from any contact with gases prevalent in the atmosphere such as ozone. Microporous film would be counterindicated because the micropores facilitate penetration of gases therethrough and therefore may not protect the underlying indicating agents.

Marino (U.S. Patent No. 4,981,653) discloses a test device in which a protective adhesive strip (numeral 52 in Figure 1) is placed over reagent threads to protect the same from ambient conditions until just prior to use. However, the adhesive strip is removed before the assay is conducted so as to expose the reagent threads to the sample (column 5, lines 47-52). To the contrary, the protective coating employed in the present invention is affixed to the substrate permanently including during the assay. It is not removed to expose the indicating agent to the sample. Quite to the contrary, the protective coating of the present invention is placed on the device after all of the elements of the assay have been incorporated on the substrate including the indicating agent. The protective coating is not removed before or during the assay. The assay can be conducted because the protective coating does not adversely affect the indicating agent and allows any

excitation wavelengths to pass therethrough which can excite the indicating agent and allows the desired detectable signal to pass therethrough without adversely affecting the same. Marino teaches an entirely different configuration in which a protective covering is used only prior to conducting the test and therefore must be removable.

Lawrence (U.S. Patent No. 5,571,684) discloses a test for detecting proline iminopeptidase in which a protective covering 59 is said in the Office Action to read on the "protective coating" of the present invention. This is not the case.

As explained beginning at column 18, line 31 of Lawrence, the embodiment of Figure 4 shows a porous sheet 41 with certain areas which permit diffusion of a reagent (51, 52 and 53). The remaining portion of sheet 41 is comprised of a barrier material so that the reagent can only travel through the porous sheet 41 in the areas designated 51, 52 and 53. Thus, the cover layer 59 is used in the same manner as described above in connection with Marino. This layer protects the device until it is time to conduct the assay at which time the cover layer 59 is removed so that the reagents can be deposited and allowed to penetrate the porous sheet 41 in the designated areas 51-53. If the cover layer 59 remained, one could not conduct the test and the device would be useless.

Barmore (U.S. Patent No. 5,483,819) is directed to a device for use in a method of detecting the permeability of an article to oxygen. Reference is made to

column 1, beginning at line 45 in which the reference device is in the form of a peelable film structure. This structure is made so that an oxygen barrier layer can be easily separated from the rest of the film structure. When the oxygen barrier layer has been removed, an underlying oxygen permeable layer is exposed and the oxygen permeability test can proceed.

Thus, the reference employs an oxygen barrier layer prior to the time of conducting the test. Once the test is to be performed so that oxygen permeability can be determined, the oxygen barrier layer is removed and all that is left is an oxygen permeable layer which enables the passage of oxygen therethrough.

In the present invention, the protective coating is affixed to the device prior to conducting the assay and remains thereon during the assay. The protective coating, even during the assay, prevents gases from contacting the indicating agent. An oxygen permeable layer can not perform this function. Accordingly, the claimed invention is neither anticipated by nor rendered obvious over Barmore.

The references discussed above disclose either a peelable layer which must be removed prior to performance of the test or disclose protective materials that can not provide a barrier against atmospheric gases. In addition, there is no teaching or suggestion of a protective coating which has the further characteristics of 1) not generating an adverse amount of undesired signals, 2) enabling passage of excitation wavelengths capable of exciting the indicating agent, and 3) enabling

passage of the desired detectable signal resulting from contact of the sample with the indicating agent. It is therefore submitted that the present application as amended is patentable over the cited prior art.

New claims 29-33 have been added to the present application to cover preferred embodiments of the invention. Support for these claims is found in the specification as follows. Claim 29 provides that the substrate can be an array substrate which is clearly disclosed in the examples appearing beginning on page 16 of the specification. The preferred substrate materials are those disclosed at page 10, lines 5-7. These materials are specifically covered by new claim 30. Claim 31 covers the preferred indicating agents which are disclosed at page 10, lines 7-10.

Claim 32 indicates that the protective coating is impervious to ozone as described on page 12, line 9. Finally, claim 33 covers the substrate in its preferred form as a microarray which is likewise covered by the examples beginning on page 16 and specifically on page 16, line 6.

In view of the foregoing, Applicants submit that the present application is in condition for allowance and early passage to issue is therefore deemed proper and is respectfully requested.

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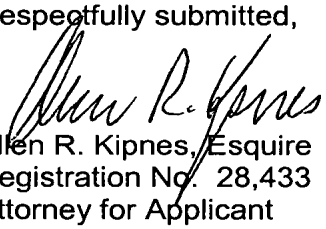
It is believed that no fee is due in connection with this matter. However, if any fee is due, it should be charged to Deposit Account No. 23-0510.

Respectfully submitted,



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